Processed Apples Institute

March 4, 2003

Mr. Stuart Shapiro
Desk Officer for the Food and Drug Administration
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th Street, NW
Room 10235
Washington, DC 20503

RE: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Docket No. 02N - 0276

Dear Mr. Shapiro:

The Processed Apples Institute (PAI) is a trade association composed of companies producing apple products: juices, sauces, flavors, essences, etc. Our members produce a major portion of the apple juice and applesauce manufactured annually in the United States. PAI submits the following comments on the cost estimates outlined in Section IV of the Food and Drug Administration's proposed regulation: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was published in the February 3, 2003, *Federal Register* (68 FR 5377).

Section IV. D. (2.)(b.)(iii) of the proposed regulation states that there are four steps associated with a domestic facility complying with the regulation. "One, the facility becomes aware of the regulation; two, the facility learns what the requirements are; three, an administrative worker fills out the form; and four, the owner, operator, or agent in charge certifies the form." As stated in Section IV, after the facility is aware of the regulation, the facility would need to find a copy of the requirements, read the requirements and understand them.

Table 38 (option 7) of the proposed regulation shows the total research cost for all domestic facilities with Internet access as $3,601,000. This cost is calculated based on one hour of research time by the administrative worker at a rate of $25.10 multiplied by 143,453 domestic facilities with the Internet. PAI comments that this cost is greatly underestimated. It may take the administrative worker one-hour to research the document; however, the cost estimate does not take into account the time to read and understand the requirements in the regulation. The administrative worker would probably not be the person reviewing the document for content or formulating a plan for implementation. This would likely be the responsibility of the manager or, in some instances, the company's legal counsel. If we estimate this process takes 10 hours of a manager's time at a rate of $56.74, this would increase the research cost of a facility with Internet access to $567.40 and the total research cost to $592.50 per facility (i.e., 1 hour of time for the administrative worker and 10 hours of time for the manager). Using option 7, this would bring the total research cost for all domestic facilities with Internet access to $84,995,902 as opposed to the proposed cost of $3,601,000. The total research cost for all domestic facilities without Internet access would be in excess of $36,000,000.

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5775 Peachtree-Dunwoody Road • Building G, Suite 500 • Atlanta, Georgia 30342
(404) 252-3663 • Fax (404) 252-0774 • E-mail: pai@kellencompany.com • www.appleproducts.org

If a company uses legal counsel to assist with the regulation, this would increase the cost of implementing the regulation even more. For example, if it took legal counsel five hours to review the regulation at a cost of $300 per hour, the cost estimate would increase by $1,500.

In the section regarding the sensitivity to assumptions, Section IV. D. 9 (a), the FDA states that the amount of time for facility employees to read and understand the requirements is a significant source of uncertainty. In Table 43, the FDA recalculated the costs by doubling the time estimates for administrative activities. This increased the total domestic costs from $13,212,000 to $19,754,000, which is still grossly underestimated.

We point out also, the time for foreign facilities to read, understand and implement the regulations must be taken into account.

We believe there also would be associated costs with manufacturing facilities communicating with vendors to assure they are aware of the regulation. As this proposed regulation would be mandatory, it is in the best interest of manufacturing facilities to ensure that they purchase products from registered facilities.

Section IV. D. (2.)(b.)(iv)
In this section, FDA estimates that 20 percent of all facilities would have to update their registration each year. PAI believes that the number of facilities that would have to update their registration each year would greatly exceed this number. Changes in product categories, company acquisitions and turnover in personnel would impact this figure.

Section IV. D. 9. (b)
The FDA has requested comments on estimating the costs for trade organizations and others to notify facilities of the registration requirements. Since June 12, 2002, PAI has submitted to its members twelve communications concerning the Bioterrorism Act and the proposed regulations. In addition, PAI's legal counsel prepared summaries regarding the Act and proposed regulations. PAI has spent numerous hours informing its members about the legislation and proposed regulations.

We appreciate your consideration of these comments.

Sincerely,

Andrew G. Ebert
President